HIGH PRECISION OPHTHALMIC COMPOSITION DROPPER TIPS AND RELATED METHODS

by

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CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of U.S. Application No. 60/540,060, filed January 30, 2004, the content of which in its entirety is hereby incorporated by reference.

BACKGROUND

The present invention relates to devices for administering compositions to an eye of a human or animal. More particularly, the invention relates to devices, including dropper tips, that deliver ophthalmic compositions to an eye of an individual with a high degree of precision and reproducibility.

To treat a patient by administering a topical ophthalmic pharmaceutical composition, the composition should be delivered as accurate and precise drops to ensure proper delivery of a pharmaceutical agent in the drop. Current ophthalmic composition dropper tips deliver drops having volumes in the range from about 35 to 50 microliters with an approximate precision of +/- 15%. Many ophthalmic formulations contain surfactants which tend to "wet out" plastic of dropper tips, and result in the production of erroneous drop size over time.

Some examples of ophthalmic composition dropper tips are disclosed in the following U.S. Patents: 5,221,027 (Gibilsco); 5,417,349 (Stull); 5,664,704

(Meadows et al.); 5,997,518 (Laibovitz et al.); 6,105,828 (Kanner et al.); 6,129,248 (Hagele); 6,197,008 (Hagele); 6,612,469 (Lopez Pardo); 6,632,202 (Hagele).

There is a need for new devices, such as dropper tips, which can administer precise amounts of medication to a patient by the dispensing of drops of compositions containing a medication onto an eye of the patient.

Summary of the Invention

New ophthalmic composition delivery devices have been discovered. The present devices include dropper tips that are structured in dispensing drops of an ophthalmic composition onto an eye of an individual. The drops are dispensed in a precise and reproducible manner which facilitates therapeutic treatment of one or more conditions of a patient.

The present dropper tips comprise a body. The body has a first end, an opposing second end, and a conduit extending therethrough. The dropper tip comprises an ophthalmic composition dispensing element located at the first end of the body. When the dropper tip is coupled to a container that contains an ophthalmic composition, the ophthalmic composition can be dispensed from the dropper tip as discrete drops. The drops have a size, such as a volume or weight, that is precisely controlled by the structure of the dispensing element and is reproducible for each dispensement of the drops.

In one embodiment, the dispensing element is structured to dispense drops having a maximum relative

deviation less than 10%. In additional embodiments, the drops have a maximum relative deviation less than 3%, and in further embodiments, the drops have a maximum relative deviation between about 1% and about 3%.

In another embodiment, the conduit of the dropper tip body comprises a flow restrictor portion and a dispensing portion. The flow restrictor portion is effective in providing dropwise dispensing of the ophthalmic composition. The dispensing element of this embodiment comprises a sidewall that is coextensive with the innerwall defining the conduit. The sidewall forms a dispensing orifice of the dispensing portion of the conduit, and has a distal end surface oriented at a substantially ninety degree angle to the longitudinal axis of the dispensing element. The thickness of the sidewall in this embodiment is substantially less than the diameter of the orifice.

The present dropper tips may also comprise a protection member structured to reduce or prevent contact between the dispensing element and a surface of the eye. The protection member may be provided as a ring structure circumscribing the dispensing element at the first end of the body.

A method of producing the present dropper tips may comprise a step of forming a material, such as hard or elastomeric materials, into a dropper tip having a dispensing element as herein described.

Each and every feature described herein, and each and every combination of two or more of such features, is included within the scope of the present invention

provided that the features included in such a combination are not mutually inconsistent. In addition, any feature or combination of features may be specifically excluded from any embodiment of the present invention.

These and other aspects and advantages of the present invention are apparent in the following detailed description, drawings, examples and claims.

Brief Description of the Drawings

FIG. 1 is a side plan view of an ophthalmic composition dropper tip comprising an ophthalmic composition dispensing element oriented along the longitudinal axis of the dropper tip.

FIG. 2 is a sectional view of the dropper tip of FIG. 1 coupled to an ophthalmic composition container.

FIG. 3 is a magnified perspective view of the ophthalmic composition dispensing element of the dropper tip of FIG. 1.

FIG. 4 is a side plan view of an ophthalmic composition dropper tip comprising a dispensing element oriented at a forty-five degree angle to the longitudinal axis of the dropper tip.

FIG. 5 is a sectional view of the dropper tip of FIG. 4 rotated by ninety degrees.

FIG. 6 is a perspective view of an ophthalmic composition dropper tip similar to FIG. 1 and including a protection member.

FIG. 7 is a sectional view of the dropper tip of FIG. 6.

FIG. 8 is a magnified perspective view of the dispensing element and protection member of the

dropper tip of FIG. 6.

FIG. 9 is a sectional view of the dispensing element and protection member of the dropper tip of FIG. 8.

FIG. 10 is a sectional view of an ophthalmic composition dropper tip similar to FIG. 5 and including a protection member.

FIG. 11 is a magnified perspective view of the dispensing element and protection member of the dropper tip of FIG. 10.

FIG. 12 is a graph illustrating drop volume (microliters) versus drop number.

FIG. 13 is a perspective view of an ophthalmic composition dropper tip including a dispensing element and protection member similar to FIG. 6.

FIG. 14 is a side plan view of the dropper tip of FIG. 13.

Detailed Description

The present invention involves devices that are useful in delivering compositions to an eye of an individual, such as a human or animal. The devices are structured or constructed to administer ophthalmic compositions, such as topical ophthalmic compositions, to a patient as drops. Examples of ophthalmic compositions useful in the present devices include liquids, solutions, formulations, suspensions, emulsions, and the like. The compositions dispensed from the present devices may include, without limitation, glaucoma drugs, dry-eye products, anti-infectives, anti-allergy medications, contact lens care solutions, saline solutions, and the like.

The drops administered by the present devices have a high degree of precision with respect to drop size. Or, stated differently, drops of the ophthalmic composition are administered at a size that is precise and reproducible from administration to administration. The precise drop size is maintained for repeated uses of the device, and is independent of the angle of orientation at which the composition is administered to the eye.

Drop formation is a function of surface tension of a composition, and drop size is determined by the diameter of the dispensing orifice of a dropper tip and flow rate of the composition. In conventional dropper tips, drop size is determined by the external surface area of the dropper tip that is in contact with the composition drop. A container to which the dropper tip is attached may also play a role in the drop size. For example, container features, such as container volume, composition volume, wall thickness, and the composition itself, may affect the drop sizes dispensed from the dropper tip.

In general, the ophthalmic composition delivery devices disclosed herein comprise an ophthalmic composition dropper tip. The dropper tip delivers an ophthalmic composition from a container in which the composition is contained, to an eye to provide a therapeutic benefit to the patient receiving the composition.

As discussed herein, existing dropper tips do not provide precise drop sizes, such as drop sizes that vary in size less than 10% relative to other drops of the same composition dispensed from the same dropper

tip. Therefore, the amount of medication administered to an eye can vary substantially from drop to drop. For example, the dropper tip disclosed in U.S. Patent No. 6,105,828 (Kanner et al.) is constructed to deliver drops in the range of 25 +/- 5 microliters. Thus, the drops delivered by the dropper tip have a relative deviation of about 20%. Similarly, other existing dropper tips provide inadequate reproducibility in drop size precision. For example, some dropper tips provide drops of ophthalmic compositions with a relative deviation of 10-15%.

In contrast, the present dropper tips are structured to deliver drops of an ophthalmic composition that have a reduced deviation compared to existing dropper tips. The present dropper tips are structured to dispense ophthalmic composition drops having a maximum relative deviation less than 10%. In certain embodiments, including the illustrated embodiments, the dropper tips are structured to dispense ophthalmic composition drops having a maximum relative deviation less than 3%. Some embodiments of the dropper tips, deliver drops with a maximum relative deviation between about 1.0% and about 3.0%. Although such deviations may not be substantial for large drop sizes, as the drop sizes decrease, the deviation becomes more critical.

Thus, the present dropper tips are relatively simple in design and are effective in dispensing small size drops with a high degree of precision and reproducibility, especially when compared to existing dropper tips. As understood from the disclosure herein, precisely sized drops can be dispensed from

the dropper tip onto a surface of an eye of a patient without any additional separate devices. For example, precisely sized drops can be delivered from the dropper tip without the use of a separate gas induction delivery device. In addition, the drops can be dispensed without regard to the formation of bubbles in the dropper tip. For example, bubbles that may form in the dropper tip do not substantially negatively affect the reproducibility and precision of the drop sizes.

Generally, the present dropper tips can be constructed to dispense drops ranging in size from about 1 microliter to about 60 microliters. However, in certain situations, dropper tips may be constructed to dispense larger sized drops. Some of the present dropper tips are structured to dispense drops ranging in size from about 5 microliters to 50 microliters. It is to be understood, that due to the high precision obtained with the present dropper tips, that different dropper tips may be needed for dispensing different sized drops. For example, a dropper tip that dispenses 5 microliter drops will be different (e.g., it will have a different structural configuration) than a dropper tip that dispenses 10 microliter drops or 20 microliter drops.

In addition, dropper tips may be capable of dispensing drops having a volume of 35 +/- 0.35 microliters, 25 +/- 0.25 microliters, or 10 +/- 0.1 microliters (e.g., drops with about a 1% relative deviation). Similarly, dropper tips that dispense drops having a 3% maximum relative deviation may dispense drops having a volume of 35 +/- 1.05

microliters, 25 +/- 0.75 microliters, or 10 +/- 0.3 microliters. Other dropper tips encompassed by the present invention may administer larger or smaller sized drops.

As used herein, "relative deviation" may be understood to refer to be the precision of drop size represented as a percentage. The relative deviation may be determined using the following equation (Equation I):

$$RD = Da/M \times 100$$

where RD is relative deviation, Da is the average absolute deviation (e.g., the average of the standard deviation of a population of drops), and M is the mean value (e.g., the mean size of the population of drops. As used herein, relative deviation may also be referred to as relative error.

Reference will now be made in detail to certain embodiments of the invention, examples of which are illustrated in the accompanying drawings. Wherever possible, the same or similar reference numbers are used in the drawings and the description to refer to the same or like parts. It should be noted that the drawings are in simplified form and are not to precise scale. In reference to the disclosure herein, for purposes of convenience and clarity only, directional terms, such as, top, bottom, left, right, up, down, over, above, below, beneath, rear, front, backward, forward, distal, and proximal, are used with respect to the accompanying drawings. Such directional terms should not be construed to limit the scope of the invention in any manner.

Although the disclosure herein refers to certain

illustrated embodiments, it is to be understood that these embodiments are presented by way of example and not by way of limitation. The intent of the following detailed description, although discussing exemplary embodiments, is to be construed to cover all modifications, alternatives, and equivalents of the embodiments as may fall within the spirit and scope of the invention as defined by the appended claims.

FIG. 1 illustrates an ophthalmic composition dropper tip 20. The dropper tip 20 comprises a body 22 having a first end 24, and a second end 26. The second end 26 is structured or constructed, such as sized and/or shaped, to be coupled to a container that contains an ophthalmic composition. The body 22 of the dropper tip 20 also has a longitudinal axis 1L, as shown in FIG. 1.

As shown in FIG. 2, the body 22 has an inner wall 28 that defines a conduit 30. The conduit 30 extends through the body 22 to pass or direct an ophthalmic composition from a container 100, which is coupled to the second end 26, to the first end 24. The container may be any conventional container suitable for containing ophthalmic compositions, preferably in a sterile condition. Examples of such containers include plastic bottles, such as squeeze bottles and the like. However, other containers may by used in conjunction with the present dropper tips. The composition is dispensed from the first end 24 as one or more drops. More specifically, the drops are dispensed from a ophthalmic composition dispensing element 32 that is located at the first end 24 of the body 22.

As shown in FIG. 2, the dispensing element 32 comprises a dispensing orifice 34, a sidewall 36, and a distal end surface 38. In general, the dispensing orifice 34 is the distal end of the conduit 30. As discussed herein, the dispensing element 32 is structured, such as being sized and shaped, to dispense drops of the ophthalmic composition in a precise and reproducible manner. That is, each drop is dispensed having approximately the same size. The size of the drop refers to the weight of the drop, the volume of the drop, or both. In contrast to existing dropper tips, the dispensing element 32 of the present dropper tip 20 is effective in dispensing drops that have a size with a maximum relative deviation less than 10 percent. As discussed herein, the relative deviation of the drops is determined by measuring the size of a population of drops, such as two or more drops, and determining the mean size of the drops of the population, and determining the mean standard deviation of the drop size for the population. The mean standard deviation of the drop size is divided by the mean drop size and is multiplied by one hundred to obtain the relative deviation in the form of a percentage. The dispensing element 32 is structured to dispense drops of the ophthalmic composition while maintaining minimal contact between the drop and the first end 24 of the body 22. In contrast to existing dropper tips, the present dropper tips dispense drops of the ophthalmic composition without the drop "rolling" or spreading across the distal end of the body 22.

FIG. 2 also illustrates that the conduit 30 may

comprise a plurality of structurally distinct portions, such as two or more portions. In the illustrated embodiments of the present dropper tips 20, the conduit 30 comprises a first portion 40 defined by a first inner wall portion 42, and a second portion 44 defined by a second inner wall portion 46. The first portion 40 may be understood to be a dispensing portion of the conduit 30. Thus, the first portion 40 is located at the first end 24 of the body 22, and is illustrated as including the dispensing orifice 34 of the dispensing element 32. The second conduit portion 44 may also be understood to be an ophthalmic composition flow restrictor portion, at least with respect to the illustrated embodiments of the present dropper tips.

The first conduit portion 40, or the dispensing portion, and the second conduit portion 44 each have diameters representing the respective sizes of the conduit portions. The portions 40 and 44 may have a substantially constant diameter along the length of the portion (e.g., the portion of the conduit may be non-tapered), or one or both portions may have multiple different diameters (e.g., the portion of the conduit may be tapered). The dispensing portion 40 of the dropper tip 20 illustrated in FIG. 2 has a maximum diameter DD that is greater than the maximum diameter SD of the second conduit portion. The dispensing portion 40 illustrated in FIG. 2 has a length extending along the axis 2L illustrated in FIG. 1, and the diameter of the dispensing portion decreases from the dispensing orifice 34 toward the second conduit portion 44. However, as shown in FIG. 14, the

dispensing portion 40 may not be tapered. In other words, the dispensing portion 40 may have a length and the diameter of the dispensing portion 40 is substantially constant along the length.

As discussed herein, at least in reference to the illustrated embodiments, the second conduit portion 44 may be understood to be a flow restrictor portion of the conduit 30. In such embodiments, the second conduit portion 44 has a maximum diameter that is less than a minimum diameter of the dispensing portion 40. In other embodiments, which do not comprise a flow restrictor portion as illustrated in the figures, the second conduit portion 44 may have a maximum diameter equal to the minimum diameter of the dispensing portion 40.

A magnified view of the dispensing element 32 is illustrated in FIG. 3. As shown in FIG. 3, the dispensing element 32 has an inner diameter ID and an outer diameter OD. The difference between the outer diameter OD and the inner diameter ID is equal to the thickness T of the sidewall 36. In order to obtain the precision in drop size disclosed herein, the thickness T of the sidewall 36 is small compared to the inner diameter ID or the outer diameter OD. In addition, the distal end surface 38 is oriented at a substantially perpendicular, and preferably at a ninety degree angle, relative to the axis 2L of the dispensing element 32.

In certain embodiments of the present dropper tips 20, the ratio of the inner diameter to outer diameter of the dispensing element 32 is greater than or equal to 0.5:1. In other words, the inner diameter

is half the size of the outer diameter. Some embodiments have a ratio of 0.93:1 (e.g., the inner diameter is 93% of the outer diameter). Thus, in reference to the present dropper tips, the dispensing element 32 may have a ratio of inner diameter to outer diameter in a range from about 0.5:1 to about 0.93:1. In specific embodiments, the ratio of inner diameter to outer diameter of the dispensing element 32 is greater than 0.75:1 (e.g., the inner diameter is greater than 75% of the outer diameter).

It may also be understood that the thickness T of the sidewall 36 may be in a range from about 0.1% to about 20% of the dispensing orifice diameter. Some embodiments of the present dropper tips 20 have a sidewall thickness T that is between about 9.0% to about 16% of the dispensing orifice diameter.

As shown in FIGS. 4 and 5, the dispensing element 32 may be oriented at a non-zero degree angle relative to the first longitudinal axis 1L of the body 22. More specifically, the embodiment of the dropper tip 20 illustrated in FIGS. 4 and 5 comprises a body having a first longitudinal axis 1L and a dispensing element 32 having a second longitudinal axis 2L. The second longitudinal axis 2L is oriented at a forty-five degree angle relative to the first longitudinal axis 1L. As shown in FIGS. 1-3, the dispensing element 32 may have a longitudinal axis 2L oriented at a zero degree angle relative to the first longitudinal axis 1L. In other embodiments, the dispensing element 32 may have a longitudinal axis oriented at a ninety degree angle relative to the longitudinal axis of the body of the dropper tip. Thus, the present dropper

tips may have a body and a dispensing element that is oriented at an angle from about zero degrees (including zero degrees) to about ninety degrees (including ninety degrees) relative to the longitudinal axis of the body.

As shown in FIGS. 6-11, 13, and 14, the present dropper tips 20 may also comprise a protection member 48 structured or constructed to prevent the dispensing element 32 from contacting a surface of an eye. The protection member 48 is illustrated as surrounding the dispensing element 32, for example, entirely surrounding the dispensing element 32. In other embodiments, the protection member 48 may partially surround the dispensing element and still provide the desired protection effect. The protection member 48 is particularly useful in embodiments in which the body of the dropper tip and/or the dispensing element is made from a relatively rigid or hard material, such as plastics and the like. In embodiments in which the body of the dropper tip, or just the dispensing element of the dropper tip, is made of a resilient or elastomeric material, protection members may not be necessary, as shown in FIGS. 1-5.

Referring back to FIGS. 6-11 and 13-14, the protection member 48 may be understood to be a ring circumscribing the dispensing element 32. The protection member 48 is illustrated as extending distally beyond the dispensing orifice 34 (see, e.g., FIGS. 9, 10, and 14). Accordingly, it may be understood that the dispensing orifice 34 is recessed relative to a distal end surface of the protection member. Thus, when the dropper tip 20 is placed near

an eye, such as above or in front of the eye, to administer one or more drops to the eye, the protection member 48 may contact the surface of the eye and would reduce the possibility that the dispensing element 32 contacts the eye. As shown in FIGS. 6-11 and 13-14, the protection member 48 may form a cavity 52 having a bottom surface 50 from which the dispensing element 32 extends. As illustrated in FIGS. 6-11, the bottom surface 50 may be radially angled or beveled. But, as shown in FIGS. 13-14, the bottom surface 50 may be substantially planar.

The precision of the drop sizes obtained with the present dropper tips can be seen in the graph of FIG. 12. To obtain the data for the graph of FIG. 12, twelve drops of three different compositions having different viscosities were dispensed consecutively from three separate dropper tips, as disclosed herein. The volume of each drop was measured. Trace 102 represents the volumes of drops of a water composition. The mean volume of the water drops was 23.9 microliters. The standard deviation of the water drops was 0.8. Therefore, the relative deviation or relative error of the water composition drops is about 3.1%. Trace 104 represents the volumes of drops of a composition having a viscosity of 15 centipoise. The mean drop volume for this composition was 22.6 +/- 0.4 microliters. The relative deviation or relative error was about 2.0%. Trace 106 represents the volumes of drops of a composition having a viscosity of 30 centipoise. The mean drop volume for this composition was 20.2 +/- 0.5 microliters, and the relative deviation or relative error was about 2.6%.

Thus, in certain embodiments, the present dropper tips 20 comprise a dispensing element 32 that is structured to dispense drops having a size with a maximum relative deviation less than about 3%. In additional embodiments, the maximum relative deviation of the drop size is in a range from about 1% to about 3%.

In view of the above, and in reference to the accompanying figures, one embodiment of the present dropper tips may be understood to comprise a body 22 having a first end 24, an opposing second end 26, and an inner wall 28 defining a conduit 30. The conduit 30 extends through the body to pass an ophthalmic composition from a container coupled to the second end 26 to the first end 24. The conduit 30 comprises an ophthalmic composition dispensing portion 40 located at the first end 24 of the body 22. The conduit 30 also comprises an ophthalmic composition flow restrictor portion 44 extending from the dispensing portion 40 towards the second end 26 of the body 22. The flow restrictor portion 44 is effective in providing dropwise dispensing of the ophthalmic composition. The dropper tip 20 also comprises an ophthalmic composition dispensing element 32 located at the first end 24 of the body 22. The dispensing element 32 comprises a sidewall 36 that is coextensive with the innerwall 28 of the conduit 30, and forms a dispensing orifice 34 of the dispensing portion 40 of the conduit 30. The sidewall 36 has a distal end surface 38 oriented at a substantially ninety degree angle to a longitudinal axis 2L of the dispensing element 32, and has a thickness T that is

substantially less than the diameter of the dispensing orifice 34.

Similar to the other embodiments described herein, this dropper tip may also comprise a protection member extending beyond the distal end surface of the dispensing element 32.

The dispensing element 32 of this embodiment is structured to dispense drops of the ophthalmic composition that have a size, such as a weight or volume, with a maximum relative deviation less than about 3 percent.

It may be understood that the dispensing element 32 is illustrated as a tubing-like member located at the first end 24 of the dropper tip body 22. The tubing-like member includes an inside diameter, a relatively thin wall thickness, and an outside diameter, as discussed herein. The tubing-like member also includes a distal end surface oriented at a substantially perpendicular angle to the longitudinal axis of the tubing-like member. The relatively thin wall and sharp edge at the distal end surface of the tubing-like member allow a composition drop to break away quickly and cleanly from the dropper tip body 22. Once the drop is dispensed from the tubing-like member, the drop usually does not come into contact with any other portion of the dropper tip under normal administration of the composition to the eye. The composition remaining in the tubing-like member returns toward the container after the drop is dispensed. The small wall thickness and thus the small surface area of the distal end surface contribute to the enhanced drop-to-drop

reproducibility of the present dropper tips.

The drop size of the present dropper tips is a function of the inner diameter of the dispensing orifice 34. The drop size of the present dropper tips is not affected by the external surface area of the dispensing tip. For comparison, existing dropper tips that have a dispensing orifice surrounded by curved surfaces or with surfaces having a relatively large area relative to the inner diameter of the orifice increase the amount of drop-to-drop variability dispensed from those tips.

The present dropper tips can be produced using conventional techniques, such as injection molding of a plastic resin material or machining of a solid plastic member. The dispensing element 32 can be integrally formed with the body 22, or can be separately manufactured and attached thereto.

Thus, a method for producing an ophthalmic composition dropper tip in accordance with the disclosure herein may comprise a step of forming a material into a body having a first end, an opposing second end, and an inner wall defining a conduit extending through the body to provide a flow path from the second end to the first end. The first end of the body is formed to include an ophthalmic composition dispensing element which comprises a dispensing orifice of the conduit. The dispensing element is formed to dispense drops of the ophthalmic composition from the body, the drops having a maximum relative deviation less than 10 percent with respect to the sizes of the drops. In certain embodiments, the dispensing element is formed to dispense drops with a

maximum relative deviation from about 1.0% to about 3.0%.

The material used to form the dropper tip body can be any conventional material currently used in the production of dropper tips. In certain embodiments of the present dropper tips, the material includes an anti-wetting agent, such as hydrophobic resins and the like, that are effective in reducing or preventing wetting effects on the first end of the body of the dropper tips. Hydrophobic resins and similar materials may also help reduce fouling or residual fluid remaining upon or within the dispensing element of the dropper tip. Non-limiting examples of materials used to form the present dropper tips include polyethylene (PE) materials, polypropylene (PP) materials, cyclic olefin materials (CZ resin), fluorinatedethylenepropylene (FEP) materials, polyvinylidene fluoride (PVDF) materials, and other medical grade materials. The material may also include an elastomeric material, such as polyisoprene, thermoplastic elastomers, silicone, and the like.

The present dropper tips 20 can be coupled to any container suitable for holding or containing an ophthalmic composition. For example, the present dropper tips can be coupled to a container, such as a bottle, by engaging the second end 26 of the body 22 with a receiving portion of the container. The bottle may be a squeeze bottle. The coupling of the dropper tip 20 to the container 100 can be obtained by a pressure or snap-fit between the dropper tip and the container, or the dropper tip can be screwed onto the container. The dropper tip may also be covered by a

screw-on or snap-on cap. Preferably, the coupling of the dropper tip to the container does not affect the sterility of the composition contained therein.

The present devices may be used by placing the present dropper tips in proximity to an eye of a patient, such as above the eye of the patient. The dropper tips are coupled to a container storing an ophthalmic composition. The ophthalmic composition is then directed from the container through the conduit 30 of the dropper tip and out of the dispensing element in the form of drops. Each of the drops has a size that is precise and reproducible. The drops can be dispensed from the dispensing element by actively urging the composition through the conduit 30, including the second conduit portion or flow restrictor portion, as in certain embodiments, and the first portion 40 or dispensing portion. For example, the composition can be urged through the conduit by squeezing the container, such as a bottle, so that the composition moves from the container to the dispensing element. Alternatively, the drops can be dispensed from the dispenser element as drops by allowing the composition to pass through the conduit 30. It may be understood that compositions that have relatively low viscosity may be more appropriate for the streaming application compared to the active urging application.

EXAMPLES

The following non-limiting examples provide those of ordinary skill in the art with specific features of dropper tips within the scope of the present invention and are not intended to limit the scope of the

invention.

EXAMPLE 1

Dropper tips which dispense predetermined volumes of drops may have structural features, as described below.

The present dropper tips may have a body having a length of about one inch or less.

In at least one dropper tip, the length of the body corresponding to the length of the dispensing portion of the conduit and the flow restrictor portion is about 0.425 inches. The length of the flow restrictor portion is about 0.100 inches. The flow restrictor portion has a maximum diameter less than or equal to 0.010 inches.

For some dropper tips which comprise a protection member, such as a safety ring, the wall thickness of the protection member is 0.050 inches. The protection member has a distal end surface that extends 0.005 inches distally beyond the distal end surface of the dispensing element.

One dropper tip which is structured to dispense 15 microliter size drops of a low viscosity composition has a dispensing orifice inner diameter of 0.030 inches, a sidewall thickness of 0.005 inches. When such a dropper tip comprises a protection member, such as a safety ring, the inner diameter of the safety ring is 0.240 inches, and the distance from the distal end surface of the dispensing element to the bottom surface of the surrounding cavity is 0.180 inches.

One dropper tip which is structured to dispense

35 microliter size drops of a low viscosity composition has a dispensing orifice inner diameter of 0.055 inches, a sidewall thickness of 0.005 inches. When such a dropper tip comprises a protection member, such as a safety ring, the inner diameter of the safety ring is 0.320 inches, and the distance from the distal end surface of the dispensing element to the bottom surface of the surrounding cavity is 0.240 inches.

One dropper tip which is structured to dispense 60 microliter size drops of a low viscosity composition has a dispensing orifice inner diameter of 0.070 inches, a sidewall thickness of 0.005 inches. When such a dropper tip comprises a protection member, such as a safety ring, the inner diameter of the safety ring is 0.380 inches, and the distance from the distal end surface of the dispensing element to the bottom surface of the surrounding cavity is 0.285 inches.

Similarly, a dropper tip that dispenses a mean 10 microliter drop size comprises a dispensing element with a dispensing orifice having an inner diameter of 0.020 inches. A dropper tip that dispenses a mean 20 microliter drop size comprises a dispensing element with a dispensing orifice having an inner diameter of 0.040 inches. A dropper tip that dispenses a mean 50 microliter drop size comprises a dispensing element with a dispensing orifice having an inner diameter of 0.065 inches.

Examples 2-15

Dropper tips in accordance with the disclosure herein provide the results shown in Table I:

TABLE I

#	ID	Angle	Drop Weight (mg)		
			Mean	SD	RD
2	0.055	45	31.5	0.5	1.6
3	0.055	90	35.0	1.1	3.1
4	0.038	45	18.5	0.4	2.0
5	0.038	90	20.3	0.5	2.2
6	0.062	90	42.5	0.5	1.2
7	0.058	90	49.0	0.9	2.0
8	0.046	90	26.2	1.0	3.8
9	0.064	45	50.1	1.0	2.0
10	0.064	90	59.8	0.9	1.7
11	0.054	45	26.2	0.7	2.7
12	0.082	90	53.0	0.7	1.4
13	0.020	45	8.5	0.09	1.0
14	0.072	45	24.8	0.9	2.8
15	0.072	90	32.1	0.7	2.8

In reference to Table I, "#" refers to the example number; "ID" refers to the inner diameter of the dispensing orifice in inches; "angle" refers to the dispensing angle of the drop in degrees; "mean" refers to the mean drop weight in milligrams; "SD" refers to the standard deviation; and "RD" refers to the relative deviation as a percent.

For each example, twenty individual drops were dispensed from the dropper tip. Each drop was weighed, and the mean drop size, standard deviation,

and relative deviation were determined. Examples 11-15 dispensed drops of deionized water, and examples 2-10 dispensed drops of publicly available ophthalmic compositions.

Embodiments of the present dropper tips may provide one or more of the following benefits or advantages: (1) drop volume formation is independent of external surface area of the first end of the dropper tip body; (2) improved accuracy and/or precision of drop sizes; (3) drop fluid does not coat the outside of the first end of the dropper tip body; (4) reduced contamination of the dropper tip; (5) drop size reproducibility is independent of viscosity of the ophthalmic composition; (6) crusting or fouling of the dispensing element does not occur, even when used with compositions comprising a high surfactant content.

In additional embodiments of the present dropper tips, a port may be provided in the conduit, such as in the dispensing portion 40, to provide enhanced functionality.

All references, articles, patents, applications and publications set forth above are incorporated herein by reference in their entireties.

While this invention has been described with respect to various specific examples and embodiments, it is to be understood that the invention is not limited thereto and that it can be variously practiced within the scope of the following claims.